

PROCEDURE FOR OBTAINING A CANNERY LICENSE

License Application Form: DHS 8597

California Health and Safety Code (H&SC) Sections 112750 and 112675 require that a canner of pH Control Foods -Acidified Low-Acid Foods (AF), and/or Thermal Process-Low Acid Canned Foods (LACF), must obtain a license issued by the California Department of Health Services' Food and Drug Branch (FDB) to operate a cannery facility in California prior to the onset of operations. The following describes what you must do or know to obtain your cannery license.

LICENSE APPLICATION

Before you submit a fully completed application form with the required fee, please read the procedures for AF and LACF below, including the procedures and requirements common to both AF and LACF (***see also license fee waiver below).

The application submission timing differs depending on the type of product being manufactured (AF and LACF), in that; laboratory testing of AF product will be necessary to confirm the product's status prior to the submission of your application. There is no charge to the canner for the initial testing done by FDB's scientific consultant at the University of California Laboratory for Research in Food Preservation. You may call the Cannery License Desk at (916) 650-6500 to receive the appropriate forms and license application (Form DHS 8597) by mail, or download the form from the FDB website: (<http://www.dhs.ca.gov/publications/forms/pdf/dhs8597.pdf> ; "Application Instructions and Forms").

Please make sure to write your firm name, license number (If the application is for renewal of your license), and the phrase "PCA Code 85124" on your check or money order. The license fee is non-refundable.

The license is valid for two fiscal years. The fiscal year begins on July 1st and ends on June 30th. The licensed canner is required to renew every two years prior to their license expiration. The business address must be that of the canning plant, not the corporate headquarters. The mailing address can be either that of the canning plant, corporate headquarters or the firm's branch office (the license will be mailed to the mailing address). An incomplete and/or illegible application will be RETURNED to the applicant.

FDB will perform an on-site inspection of the plant before issuing a license to assure that the canning facility meets the requirements specified in the Cannery Statutes (H&SC 112650 et seq) and the California Code of Regulations (Title 17 CCR Section 12400 et seq).

If you are canning pH Controlled AF products, you will be required to meet the federal regulations in Title 21 Code of Federal Regulations Part 114.

If you are canning LACF products, you will be required to meet the federal regulations in Title 21 Code of Federal Regulations Part 113.

If your AF and/or LACF product contains fish and fishery products, you will also be required to meet the federal HACCP (Hazard Analysis Critical Control Point) regulations in Title 21 Code of Federal Regulations Part 123.

THE LICENSE INSPECTION

Applicants will be contacted by FDB personnel within 3 to 4 weeks of the submission of their license application, to schedule an initial licensing inspection. During the license inspection process, FDB will inspect for adequacy of facilities, equipment, personnel qualifications, personnel practices, manufacturing procedures and controls, overall sanitation, ingredients and raw materials, container coding, container integrity, labeling, production record keeping, storage and distribution processes, and registration with FDA. FDB will insure that each AF and LACF product meets its requirements in the Official Scheduled Process issued by FDB and that each of the products are identified by a unique number. The number is generated by the U.C. Laboratory and maintained by FDB throughout the history of each specific AF and/or LACF product. FDB will also insure that each lot/batch of AF and/or LACF product is properly documented on pre-numbered and initialed production records. The production records and LACF cook charts MUST be numbered in sequence beginning with number 1 for the period July 1 through June 30 of the following year. FDB personnel will number and initial the production records and charts prior to actual production, so that these records will be ready for the canner to use. The production records will document all critical data for each lot/batch of AF and/or LACF product as required by the Official Scheduled Process, including name of canner, date of pack, product name, person(s) responsible for processing, total number of containers packed, container integrity testing records and distinct code for each product. The container code can consist of any combination of numbers or letters, but the following information must be identified: (a) the plant (or company) where product is processed; (b) the year of pack; (c) a distinct product code; (d) the date of pack; and, (e) batch or cook code. (Please note: it is recommended that, unless there is a distinct batch manufactured, the batch number be changed every 2 hours.)

You will be contacted to schedule a license inspection within a few weeks of the submission of your license application.

*****Cannery License Fee Waiver:** The cannery license fee may be waived if you can provide a photocopy of your valid California Processed Food Registration Certificate. The registration is mandatory for all food processors and wholesalers of processed food (H&SC 110460).

PROCEDURES FOR AF AND LACF

I. pH Controlled Acidified Foods (AF)

By regulation, canned Acidified Foods (AF) are defined as, “low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, “pickles” or “pickled _____.” Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded.”

If your product could be an AF, it is recommended that you review the GENERAL REQUIREMENTS FOR pH CONTROL OF LOW-ACID FOODS. These requirements can be downloaded from FDB’s website: <http://www.dhs.ca.gov/fdb/HTML/food/canneryphcontrols.htm>.

The requirements include GUIDELINES FOR pH SAMPLE SUBMISSION. You must first submit a complete “Request For pH Control” form along with two samples of your product to the State’s consulting Laboratory for evaluation. The samples and completed form should be sent to:

**University of California, Davis
Laboratory For Research In Food Preservation
(UCLRFP)
6363 Clark Avenue
Dublin, CA 94568-3097
(925) 828-1790**

The form can be obtained from the nearest FDB office or the FDB website at <http://www.dhs.ca.gov/ps/fdb/PDF/Request%20for%20PH%20Control%203%202003.PDF> . UCLRFP will evaluate the product, formulation, and processing data that the canner has provided and recommend the appropriate scheduled process to FDB. In response, FDB will generate an Official Scheduled Process letter containing a unique number and forward the letter to the potential canner. If the recommendation is that the product need NOT be packed under pH control, then the specific product will not be covered under the Cannery Inspection Program, but still must be manufactured in a food processing facility registered under FDB’s Processed Food Registration Program (PFR). Please call the nearest FDB office for registration information and an application form.

Please allow 4-6 weeks for review of samples submitted to UCLRFP.

II. Thermal Process – Low Acid Canned Foods (LACF)

By regulation a Low Acid Canned Food (LACF) is defined as, “any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.”

If your product could be LACF, it is recommended that you review the GENERAL REQUIREMENTS FOR THERMALLY PROCESSING LOW ACID CANNED FOODS. These requirements require the canner to complete and submit the “REQUEST FOR OFFICIAL STERILIZATION PROCESS” form to the State’s consulting Laboratory for evaluation:

**University of California, Davis
Laboratory For Research In Food Preservation
(UCLRFP)
6363 Clark Avenue
Dublin, CA 94568-3097
(925) 828-1790**

After submitting the cannery license application, the canner of an LACF must submit a completed “Request for Official Sterilization Process” form for each product to UCLRFP. This form can be obtained from the nearest FDB office or UCLRFP. In response, a UCLRFP scientist will call the applicant to set-up an appointment to visit the canning facility to evaluate the proposed process, processing equipment and conduct thermal heat penetration studies. The scientific data derived from this in depth evaluation will be used by UCLRFP to establish a scheduled process recommendation for FDB. From the recommendation, FDB will generate the Official Scheduled Process letter for the canner with a unique number that is specific to a product and canner. This process letter is mailed to the canner and it will contain the mandatory product-processing requirements.

LACF canners must have permitted retort operators to operate their retort or aseptic systems. Operators are given written and practical examinations on equipment operation, by the Food and Drug Branch. Upon successful completion of both exam components, operators will be issued the permit.

PROCEDURES/REQUIREMENTS COMMON TO BOTH AF AND LACF CANNERIES

Important Note: Sample product formulations and/or trade secrets that are inspected, reviewed and/or submitted to either UCLRFP and/or FDB are protected by law. H&SC 110165 makes it unlawful for any person to use to his own advantage, or to reveal to any person other than to the director or officers or employees of this department, or to the courts when relevant in any judicial proceeding under this division, any information acquired under authority of this division concerning any method or process which as a trade secret is entitled to protection.

All licensed canneries under the California Cannery Inspection Program must meet the following requirements:

- Both AF and LACF canneries must comply with applicable laws and regulations, including the requirement that a plant specific container lot coding system be submitted to FDB. The product container coding system must address the requirements in regulation, such as, any combination of numbers or letters to identify: (a) the plant (or company) where product is processed; (b) the year of pack; (c) a distinct product code; (d) the date of pack; and, (e) batch or cook code. The coding system must accommodate a change in batch numbers every 2 hours.
- All batches/lots of AF and/or LACF products produced under the Cannery Inspection Program must first be inspected and released by FDB prior to distribution. This means that the licensed cannery MUST notify FDB at least 48 hours in advance of any scheduled production of AF or LACF products. FDB will arrange to inspect the facility and audit production records, shortly after the product was produced. FDB will also test AF products for pH and may draw samples for laboratory testing.
- The licensed AF and/or LACF canner must report any known product spoilage and/or product related foodborne illness to FDB in a timely manner. The canner must also report any product recall and/or market withdrawals of regulated products to FDB.
- All fish and seafood AF and/or LACF products produced at a licensed cannery must also meet the federal Hazard Analysis and Critical Control Point (HACCP) requirements in Title 21 Code of Federal Regulations, Part 123, before the products will be released by FDB.
- All AF and/or LACF products shall be produced at a licensed cannery under the supervision of at least one person who has passed the prescribed course of instruction and training requirements specified in 21 CFR 113.10 and/or 21 CFR 114.10 (Better Process Control School).
- Licensed canners must pay for all costs of inspection, including in-plant inspection and travel time to the facility by the investigator. The fees include the cost of laboratory services provided by UCLRFP. The canner will be billed on a monthly basis. As specified in law, the Cannery Inspection Board establishes the hourly rate for inspection. The rate currently starts at approximately \$120 per hour.
- All California licensed canners trading in interstate commerce must be registered as a Food Canning Establishment (FCE) with the U.S. Food and Drug Administration (FDA). Canners are also responsible for registering all of their AF and LACF products with FDA. For FDA registration, contact the FDA at (202) 205-5282, visit their website: <http://www.cfsan.fda.gov/~comm/lacf-toc.html#guides>

or write to:

LACF Registration Coordinator (HFS-618)
U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
200 C Street, SW
Washington, DC 20204

- If your product is not subject to the FDB's cannery inspection program (**not AF or LACF**) as determined by laboratory and FDB evaluation, then the canned food product must be manufactured in a food processing facility registered with FDB's **Processed Food Registration Program (PFR)**. Please call (916) 650-6500 for PFR registration information and an application form. You may also obtain information about the PFR program at: <http://www.dhs.ca.gov/fdb/HTML/food/procfdrg.htm>.

For additional information and questions, please call or contact FDB at one of the following offices:

FOOD AND DRUG BRANCH OFFICES

FDB Food Safety Inspection Unit – Northern Region

100 Paseo de San Antonio, Room 304, San Jose, CA 95113
Telephone: (408) 277-1832; Fax: (408) 277-1141

FDB Food Safety Inspection Unit – Southern Region

1449 West Temple Street, Room 224, Los Angeles, CA 90026
Telephone: (213) 580-5720; Fax: (213) 580-5750